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US

(71) Applicant: IDEXX LABORATORIES, INC. [US/US]; One Idexx Drive, Westbrook, ME 04092 (US).

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(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

With international search report.

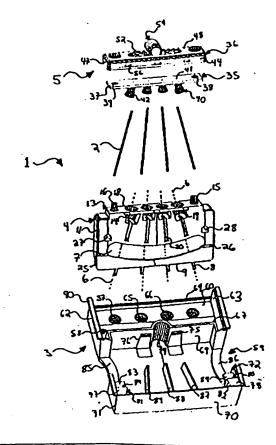
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

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(54) Title: IMMUNOASSAYS IN CAPILLARY TUBES

(57) Abstract

A fluorescent immunoassay employing the interior surface of a capillary tube is provided. Devices to permit immunoassays using one or more capillary tubes, an apparatus for use with the devices, and a process for screening for analyte in a sample using the devices and apparatus are also provided. Samples suspected of containing analyte are added to a disposable self-contained sample tray containing one or more sample wells, mixed with a reagent, drawn into one or more spacedapart capillary tubes held within a disposable cartridge connected to an analytical apparatus, reacted with a binding member on the surface of the capillary tube, washed to stop the reaction, and dried by the apparatus. The capillary tube is then exposed to a signal generation device to create a fluorescence signal that is detected using a signal detector. The apparatus determines the presence of the analyte and optionally determines the amount of analyte present in the sample, and presents the results to the operator.



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A CLASSICATION OF THE STATE OF	PC1/US 97/12/37		
A CLASSIFICATION OF SUBJECT MATTER IPC 6 G01N33/543 B01L9/06 G01N33 G01N21/03 //G01N33/94,G01N33/			
According to International Patent Classification (IPC) or to both national classification	fication and IPC		
B. FIELDS SEARCHED			
Minimum documentation searched (classification system followed by classific IPC 6 B01L G01N	ation symbols)		
Documentation searched other than minimum documentation to the extent that	t such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data to	; base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category • Citation of document, with indication, where appropriate, of the n	elevant passages Relevant to claim No.		
X WO 95 21382 A (FIELDS ROBERT E)	,,_,_,		
A see abstract; figures	45 20,35, 46,47		
x EP 0 320 385 A (MELET SCHLOESING	C (AD) 14		
X EP 0 320 385 A (MELET SCHLOESING June 1989	G LAB) 14 1,9		
A see abstract; figure 1	6,23,35, 45,46		
X US 4 116 638 A (KENOFF MICHAEL 8 September 1978	1,9,20, 21,27,46		
A see the whole document	23,35		
	-/		
	•		
X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.		
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later than the priority date claimed	*&" document member of the same patent family		
Date of the actual completion of the international search 30 March 1998	Date of mailing of the international search report 2 0, 04, 98		
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentiaan 2	Authorized officer		
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Ins. .tional Application No PCT/US 97/12737

		PCT/US 97	//12/3/
(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
(DE 33 42 428 A (HERAEUS CHRIST GMBH) 5		1
	June 1985	_	
A	see abstract; figures	; ; ;	6,22,23, 35,45
X A	WO 93 19928 A (ABBOTT LAB) 14 October 1993 see claims 13-30; figure 10	!	11-13 37
X	WO 83 01119 A (COMMW SERUM LAB COMMISSION) 31 March 1983		20,21, 27,46
A	see the whole document		22,23, 31,45
X	EP 0 103 426 A (BLOCK MYRON J) 21 March 1984		20,25, 27, 46-48, 56,57
	see abstract see page 2, line 7 – line 18		
P,X	US 5 624 850 A (KUMAR AMIT ET AL) 29 April 1997	•	20,21, 24,25, 27, 46-48,
A	see column 2, line 35 - line 53 see column 3, line 5 - line 37 see column 6, line 1 - line 10 see column 9, line 25 - line 30; examples		54,56, 57,63 53,62
		-	
·			

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information on patent family members

Im. .tional Application No PCT/US 97/12737

			3//12/3/
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9521382 A	10-08-95	AU 1745495 A CA 2182513 A EP 0752105 A JP 9511572 T	21-08-95 10-08-95 08-01-97 ; 18-11-97
EP 0320385 A	14-06-89	FR 2624615 A AT 107541 T CA 1306218 A DE 3850368 D DE 3850368 T JP 1288769 A US 5047210 A	16-06-89 15-07-94 11-08-92 28-07-94 20-10-94 21-11-89 10-09-91
US 4116638 A	26-09-78	NONE	
DE 3342428 A	05-06-85	NONE	*************
WO 9319928 A	14-10-93	US 5376313 A AU 3929093 A AU 3934393 A AU 3935093 A AU 3967793 A AU 3968093 A AU 3968093 A CA 2129245 A CA 2129246 A CA 2132959 A CA 2132960 A EP 0755519 A EP 0634016 A EP 0637283 A EP 0746769 A EP 0632894 A EP 0632896 A JP 7505473 T JP 7505475 T JP 7505476 T JP 7506184 T	27-12-94 08-11-93 08-11-93 08-11-93 08-11-93 08-11-93 14-10-93 14-10-93 14-10-93 29-01-97 18-01-95 08-02-95 11-12-96 11-01-95 15-06-95 15-06-95 15-06-95 15-06-95 06-07-95

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PCT/US 97/12737

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows: See further information
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest. X No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

- 1. Claims: 1-19; 31-34; 45(partly)
 An (semi-)automated apparatus for screening an analyte in a sample, with a cartridge for holding a plurality of spaced-apart capillary tubes, and a tray for holding multiple portions of a sample.
- 2. Claims: 20-30; 46-64; 45(partly)
 A process to analyse an analyte in a sample by a fluorescently-labelledconjugate binding-assay in a capillary tube, said capillary tube being at
 least partly coated on its inner surface with a substrate capable of
 binding to a fluorescently-labelled conjugate, on at least portion of its
 interior surface and a process for preparing a glass capillary tube.

Information on patent family members

In. ational Application No PCT/US 97/12737

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9319928 A	<u> </u>	WO 9320440 A	14-10-93
		WO 9320444 A	14-10-93
. •		WO 9320443 A	14-10-93
		WO 9320441 A	: 14-10-93
		WO 9320450 A	14-10-93
		US 5358691 A	25-10-94
and the second		US 5646049 A	08-07-97
		US 5635364 A	03-06-97
		US 5605665 A	25-02-97
	•	US 5575978 A	. 19-11-96
		US 5627522 A	06-05-97
		US 5536471 A	16-07-96
•		US 5507410 A	16-04-96
		US 5540890 A	30-07-96
		US 5482861 A	09-01-96
		US 5610069 A	11-03-97
		US 5578494 A	26-11-96
		US 5451528 A	19-09-95
WO 8301119 A	31-03-83	AU 8855182 A	12-05-83
		CA 1189449 A	25-06-85
		DK 233983 A .	25-05-83
		EP 0089346 A	28-09-83
		JP 58501521 T	08-09-83
EP 0103426 A	21-03-84	US 4447546 A	08-05-84
		JP 1809121 C	10-12-93
		JP 5021185 B	23-03-93
		JP 59081560 A	11-05-84
US 5624850 A	29-04-97	NONE	